

REMARKS

Support for the amendments

The amendments to the specification merely bring the application into compliance with 37 C.F.R. §1.821-§1.825 and thus do not constitute new matter.

The amendment to claim 10 merely clarifies the nature of the claim and is supported throughout the specification, for example on page 4, paragraph 1, and thus does not constitute new matter.

Sequence Requirements

The Office Action has objected to the application for failing to comply with the requirements of 37 CFR 1.821 through 1.825. The Applicants enclose herewith a Sequence Listing in compliance with 37 CFR 1.821 through 1.825 and have amended the specification accordingly, thus obviating the objection.

Rejection of claims 10-11 under 35 U.S.C. § 102(b)

The Office Action has rejected claims 10 and 11 under the assertion that they are anticipated by Sarkisov et al. (US Patent No. 4,368,191). The Applicants respectfully traverse. In order to anticipate a claim, a reference must teach each and every element of the claim. MPEP 2131. Sarkisov teaches a vaccine for and a method of treatment of trichophytosis in fur-bearing animals. Furthermore, the vaccine is directed toward a pathogenic agent that causes dermatomycoses of animals (i.e. is targeted to animal skin).

Sarkisov does not teach each and every element of claim 10 and its dependent claim 11. Specifically, Sarkisov does not teach a method of inducing in a human a systemic immune response and a local immune response of IgA, IgG or IgM antibodies or B cells secreting said antibodies, the method comprising parenterally administering to a human subject's thigh a composition comprising an immunogen of a pathogenic agent having a gateway into the rectal, genital and/or urinary mucous membranes in an amount effective to elicit said immune response. Thus, as Sarkisov is not a proper anticipatory reference, the Applicants respectfully request the Office withdraw the rejection of claims 10-11 under 35 U.S.C. § 102(b).

Rejection of claims 10-15 under 35 U.S.C. § 103

The Office Action has rejected claims 10-15 under 35 U.S.C. 103(a) under the assertion that they are unpatentable over Carrano et al., Groswasser et al., Stites et al., and Bouvet et al. The Applicants respectfully traverse.

In order to establish a *prima facie* case of obviousness, the prior art references when combined must teach or suggest all the claim limitations. Claim 10, and thus its dependent claims 11-15, recite “[a] method of inducing in a human a systemic immune response and a local immune response of IgA, IgG or IgM antibodies or B cells secreting said antibodies that is targeted at the rectogenitourinary mucous membrane and the lymph nodes which drain it, the method comprising parenterally administering to a human subject’s thigh a composition comprising an immunogen of a pathogenic agent having a gateway into the rectal, genital and/or urinary mucous membranes in an amount effective to elicit said immune response.” None of the cited references, alone or in combination, teach or suggest a method of inducing a local immune response that is targeted at the rectogenitourinary mucous membrane and the lymph nodes which drain it.

Carrano et al. teaches a method of immunizing an individual against HIV via direct genetic immunization, but nowhere does Carrano teach or suggest the induction of a local immune response of IgA, IgG or IgM antibodies or B cells secreting said antibodies that is targeted at the rectogenitourinary region and the lymph nodes that drain it. In fact, Carrano teaches away from the present invention. In a preferred method taught by Carrano, multiple inoculants are administered to different cells, preferably at sites different from each other (see page 37, lines 30-32). Thus Carrano teaches away from the *targeted* immune response of the present invention.

Groswasser et al. does nothing to cure this deficiency, as it merely teaches that in some cases, intramuscular injection of vaccines in infants and children is preferable over subcutaneous injection in avoiding or reducing possible reactions at the immunization site and in creating a better immune response. Nowhere does Groswasser teach or suggest a method of inducing in a human a systemic immune response and a local immune response of IgA, IgG or IgM antibodies or B cells secreting said antibodies that is targeted at the rectogenitourinary mucous membrane and the lymph nodes which drain it.

Similarly, Stites et al. does not cure the deficiency of Carrano et al. Stites et al. merely teaches that injection of vaccines into the anterolateral thigh or deltoid site is preferable to the

buttocks as such a means of injection avoids the occasional inadvertent administration of the vaccine into fat rather than muscle. Nowhere does Stites et al. teach or suggest a method of inducing in a human a systemic immune response and a local immune response of IgA, IgG or IgM antibodies or B cells secreting said antibodies that is targeted at the rectogenitourinary mucous membrane and the lymph nodes which drain it.

Furthermore, Bouvet et al. does not cure the deficiencies of Carrano et al., Groswasser et al, and Stites et al. in teaching or suggesting all the claim limitations of the present invention as required in establishing a *prima facie* case of obviousness. Bouvet et al. teaches that parenteral injection of the tetanus toxoid vaccine leads to *systemic* immune response, including the presence of *systemic*-derived IgG antitoxins in vaginal secretions. Nowhere does Bouvet teach or suggest a method of inducing in a human a systemic immune response and a local immune response of IgA, IgG or IgM antibodies or B cells secreting said antibodies that is targeted at the rectogenitourinary mucous membrane and the lymph nodes which drain it.

Hence the cited references, either alone or in combination, do not teach or suggest all the claim limitations of the present invention, and a *prima facie* case of obviousness cannot be established.

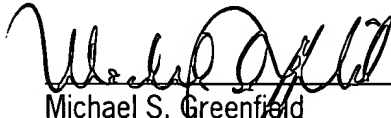
Furthermore, the presence of an unexpected property is evidence of nonobviousness. MPEP 716.02(a). The present invention possesses the unexpected property of being able to induce a *local* immune response (i.e. in the rectogenitourinary mucous membrane and the lymph nodes which drain it) by injecting an immunogen at a site distant from the rectogenitourinary_mucous membranes (i.e. the thigh). (See page 2, final paragraph). None of the prior art cited by the Office teaches or suggests such a property.

Therefore the Applicants respectfully request the Office withdraw the rejection of claims 10-15 under 35 U.S.C. § 103(a).

Given the above, the applicant believes the application is in condition for allowance. If there are any questions or comments regarding this Response or application, the Examiner is encouraged to contact the undersigned attorney as indicated below.

Respectfully submitted,

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